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CLINICAL REPORT

Modified constraint induced therapy: A randomized feasibility and efficacy study

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Abstract—This case series examined the feasibility and efficacy of a modified constraint induced therapy (CIT) protocol administered on an outpatient basis. The Fugl-Meyer Assessment of Motor Recovery After Stroke (Fugl), Action Research Arm Test (ARA), Wolf Motor Function Test (WMFT), and Motor Activity Log (MAL) were administered to six patients between 2 and 6 months poststroke (CVA) exhibiting stable motor deficits and learned nonuse of the affected limb. Two patients then participated in half-hour physical and occupational therapy sessions three times/week for 10 weeks. During the same period, their unaffected arms and hands were restrained 5 days/week during 5 hours identified as times of frequent use. Two other patients received regular therapy and two control patients received no therapy. The ARA, Fugl, WMFT, and MAL were again administered after 10 weeks. Patients receiving modified CIT exhibited substantial improvements on the Fugl, ARA, and WMFT, as well as increases in amount and quality of use of the limb using the MAL. Patients receiving traditional or no therapy exhibited no improvements.

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Results suggest that modified CIT may be an efficacious method of improving function and use of the affected arms of patients exhibiting learned nonuse.

Key words: exercise training, motor skills, rehabilitation, stroke.

INTRODUCTION

Upper-limb hemiparesis (ULH) after stroke (CVA) is one of the most prevalent diagnoses treated by therapists (1,2). The traditional view of neurologic rehabilitation is that it reduces impairment and minimizes disability. However, several factors compromise the efficacy of CVA rehabilitation. First, intensive rehabilitation is expensive, and limited financial resources exist to pay for therapy after CVA. Second, the treatments provided to patients during therapy sessions cover a wide range of disciplines such that repetitive practice in a particular area is often not provided. Furthermore, on an outpatient basis, therapy for the upper limb is often only administered 2–3 times/week for 1/2 hour each, with single therapists frequently working with several patients at one time. Skills learned during

sessions may also result in a determination of independence in the clinic, yet the patient may still not be able to function independently, and/or the individual's quality of life may remain low (3). Given these shortcomings, it is unsurprising that controlled studies evaluating physical and occupational therapy regimens for CVA have not yielded positive findings (4).

Beginning with animal research conducted during the 1970s (5–6), authors have suggested that a limb thought to be unusable is capable of movement by conditioning its use. Specifically, researchers (7–11) have restrained the unaffected arms of chronic patients with CVA for 14 hours each day for 2 weeks while having patients perform purposeful activities with the affected arm for 6 hours/day on 10 consecutive weekdays. The results of these studies, a randomized, controlled study (12), and a case study (13) suggest that this constraint-induced movement therapy (CIT) overcomes "learned nonuse," (6) and increases use and function of the affected upper limb after CVA.

Findings from a survey measuring patients' and therapists' opinions of CIT (14), however, suggest that, although efficacious, CIT's effectiveness may be limited. Specifically, when CIT was described using an excerpt from a case report (13): (1) 68 percent of patients with CVA said that they would not want to participate in the protocol; (2) two-thirds of the patients who said that they would participate in the CIT protocol conceded that they were somewhat or extremely unlikely to adhere to the CIT protocol; and (3) over 80 percent patients felt that, if the protocol lasted for more weeks with shorter PT/OT sessions and/or less hours wearing the slings, they would participate. Among therapists surveyed, over 60 percent felt that patients were extremely unlikely to adhere to such a protocol, with the primary reasons being length of time wearing a restrictive device and number of therapy hours.

Moreover, a majority of therapists felt that many facilities did not have the resources available to execute such a protocol. In expressing reservations about the constraint schedule, therapists expressed concern with compromises in independent activities (e.g., walking with a cane, driving) that patients would have to make to wear the restrictive device for all waking hours. Such a device use schedule was also speculated to compromise safety in mobility activities, such as stair climbing or walking. With regard to the practice component, therapists noted that some clinics may lack adequate resources or personnel to challenge patients for 6 hours/day.

Statement of the Problem

The CIT approach proposed by Taub and colleagues appears to have efficacy, particularly in chronic stroke (8–12). However, an effective CIT protocol would enable a large number of clinics to employ CIT with patients with CVA as part of a reimbursable therapy regimen without increasing patient attrition or compromising staffing. Motor learning researchers have also noted that a number of alternative practice schedules can elicit similar outcomes (15). Since most patients receive therapy on an outpatient basis 2-3 times per week for 1-2 months, Page and colleagues (16) recently tested a modified CIT protocol on two patients 5 months post-CVA exhibiting stable motor deficits and learned nonuse in their affected upper limbs. A 10-week regimen featuring half-hour physical and occupational therapy sessions was provided 3 times/week. This therapy schedule was combined with wearing a sling and mitt on the unaffected upper limb 5 days/week for 5 hours initially identified as a time of frequent use. Besides this therapy being implementable within most managed care guidelines, Page and colleagues (16) reported substantial decreases in impairment as well as increases in upper-limb use and function.

This case series extends the work of Page and colleagues (16). Specifically, the purpose of this study was to utilize randomized, controlled methods in (a) examining the feasibility of performing Page and colleagues' (16) protocol; (b) comparing the efficacy of Page and colleagues' (16) 10-week CIT protocol with a 10-week regimen of traditional physical and occupational therapy (TR), and with no treatment (CON), in improving scores on the WMFT and MAL; and (c) comparing the efficacy of CIT, TR, and CON with the use of established outcome measures of impairment and functional outcome. It was hypothesized that participants in the modified CIT group would exhibit greater reductions in impairment, greater increases in arm use, and greater functional improvements in the affected upper limb, than participants in the TR or CON conditions.

METHOD

Instruments

The Fugl-Meyer Assessment of Motor Recovery After Stroke (Fugl) (17) assesses several dimensions of impairment and has been extensively used in studies measuring recovery in patients with CVA, including the only randomized, controlled trial of CIT (12). The

66-point upper-limb motor component of the Fugl was used in this study. Its specific items were derived from the Brunnstrom stages of post-CVA motor recovery (18), with data arising from a 3-point ordinal scale (0=cannot perform; 1=can perform partially; 2=can perform fully) applied to each item. The Fugl has been used extensively as a measure of impairment in studies measuring functional recovery in patients with strokes (12), has been shown to have impressive test-retest reliability (total=0.98-0.99; subtests=0.87-1.00) (19), interrater reliability, and construct validity (20). The Action Research Arm Test (ARA) (21) is a 19-item test divided into four categories (grasp, grip, pinch, and gross movement), with each item graded on a 4-point ordinal scale (0=can perform no part of the test; 1=performs test partially; 2=completes test but takes abnormally long time or has great difficulty; 3=performs test normally) for a total possible score of 57. The test is hierarchical in that, if the patient is able to perform the most difficult skill in each category, then he/she will be able to perform the other items within the category and, thus, need not be tested. The test provides ordinal-level scores, has intrarater (r=0.99) and retest (r=0.98) reliability (21), can be completed in a short amount of time, and is highly correlated with many functional measures of stroke outcome (22). The ARA has also been used in CIT research (12). Using the protocols of Wolf and colleagues (7) and Taub and colleagues (8), the Wolf Motor Function Test (WMFT) was used to measure the ability of patients to perform 19 simple limb movements and tasks with the affected arm. Two of the items measure strength, and 17 items are timed and scord by a rater blinded to the pretest or posttest treatment status of the patient. It has been widely used in CIT studies (8–13). The *Motor Activity* Log (MAL) consists of a semistructured interview measuring how patients use their affected limb for ADLs in the home. In separate MAL interviews, the patient and caregiver are asked to independently rate how much and how well the patient has used the affected arm for 30 ADLs during the past week. Patients and caregivers use a 6-point Amount of Use (AOU) scale to rate how much they are using their affected arm and a 6-point Quality of Movement (QOM) scale to rate how well they are using it. Tasks include classic ADLs, such as brushing teeth, buttoning a shirt/blouse, and eating with a fork or spoon.

Subjects and Screening

Letters of recruitment were sent to patients who had experienced a CVA and were discharged from outpatient

therapy provided at four rehabilitation hospitals. A blinded research assistant with 3 years experience administering the screening tools screened individuals who had responded to the letter of recruitment for inclusion in the study. Motor inclusion criteria from previous CIT studies (8,11) were applied to determine inclusion by the blinded examiner. Criteria included ability to extend at least 10° at the metacarpophalangeal and interphalangeal joints and 20° at the wrist (the focal criterion). Other inclusion criteria, used in previous work (16), were (1) stroke experienced between 4 weeks and 6 months prior to study enrollment; (2) a score of 70 or higher on the Modified Mini Mental Status Examination (23); (3) no hemorrhagic or bilateral lesions (including individuals with contralateral lacunes), or lesions in the primary sensory or motor cortical areas; (4) age between 18 and 95; (5) no excessive spasticity, as defined as a score of "2" or higher on the Modified Ashworth Spasticity Scale (24); (6) no excessive pain in the affected upper limb, as measured by a score of "4" or higher on a Visual Analog Scale; (7) completely discharged from all forms of physical rehabilitation; and (8) not participating in any experimental rehabilitation or drug studies. The participants described herein were chosen because they met inclusion criteria, were motivated, and were willing to follow intervention guidelines.

Six patients (3 men; mean age 55.8±11.6 years, age range 44 to 77 years; mean duration of hemiparesis 4.6 months, range 2 to 5.5 months) with subacute CVA (<6 months) meeting the above criteria participated. Comparison between observations at time of screening, discharge records, and physiatrist observations determined that all patients' physical and cognitive conditions had not changed from discharge. The patients were all capable of moving their affected arms outside of synergy. However, informal interviews, clinical judgment during screening, and formal assessment with the use of the Motor Activity Log (MAL) revealed that no attempts were being made to use the affected arms. It was, thus, concluded that they were exhibiting learned nonuse (6). Demographic data are depicted in **Table 1**.

Design and Intervention

A multiple baseline, randomized pretest and posttest control group design was applied, with all subjects randomly assigned to one of three groups with equal probability. First, after receiving a detailed explanation of the study, eligible volunteers signed informed consent forms approved by the local institutional review board. The Fugl

Table 1. Subject characteristics.

Subject	Gender	Age	Onset (months)	Side affected	Group
1	F	52	5.5	R	CIT
2	M	58	5.8	L	CIT
3	M	56	5.5	L	TR
4	F	48	2.0	R	TR
5	F	77	5.0	R	CON
6	M	44	4.0	R	CON

and ARA were then administered to all subjects on two occasions during the pretesting period, while the WMFT and MAL were administered during one pretesting session. A blinded examiner administered all instruments.

Per the recommendations of Page and colleagues (16), the four patients randomly assigned to the CIT and traditional rehabilitation (TR) conditions each participated in one half hour of physical therapy (PT) and one half hour of occupational therapy (OT) on an outpatient basis three times/week for 10 weeks. Eighty percent of each PT and OT session (24 minutes) focused on neuromuscular facilitation (PNF) techniques with emphasis on ADL tasks whenever possible, and 20 percent (6 minutes) focused on compensatory techniques using the unaffected side (i.e., reaching and performing functional tasks with the unaffected arm, assisting the weak arm during reaching tasks).

"Shaping" is a commonly used operant conditioning method in which a behavioral (in this case "movement") objective is approached in small steps of progressively increasing difficulty. The participant is rewarded with enthusiastic approval for improvement, but never blamed (punished) for failure. In CIT, a basic principle is to keep extending motor capacity a small increment beyond the performance level already achieved. In addition to other tasks practiced during therapy sessions, each CIT patient identified two functional tasks listed on the WMFT that were valued by them, and these tasks were recorded on the subject data sheet. During therapy sessions, each previously identified skill was practiced for at least 5 minutes as part of the upper-limb program. One occupational therapist and one physical therapist, each with 10 years experience, administered therapy. Both were blinded to patients' group assignments.

During the same 10-week period, the lower arms and hands of the two patients randomly assigned to the CIT condition were restrained every weekday for the

5 hours initially identified as a time of frequent arm use. The arm was restrained using a cotton Bobath sling. The sling had a single strap worn around the neck and under the arm supporting the elbow and the forearm. The hand was placed in a mesh polystyrene-filled mitt with a Velcro strap around the wrist (Sammons-Preston).

After initial screening, instrument administration, and random assignment, patients randomly assigned to the control condition (CON) received no therapy during the same 10-week period. After 10 weeks, all patients returned to the laboratory, where they were again administered the Fugl, ARA, WMFT, and MAL by the blinded examiner.

RESULTS

An initial purpose of this study was to examine the feasibility of the modified CIT protocol. In-clinic interviews every 2–3 weeks, weekly telephone calls to the home of the patients assigned to CIT, and a sling wear log, all administered during participation in the protocol, revealed that adherence to the sling wear schedule by patients in the CIT group was not an issue. Informal interviews also revealed high satisfaction with the protocol, while the sling wear log also showed that CIT patients were actively attempting to use their arms during the 5 hours per day when the sling was being worn.¹

Scores on the Fugl and ARA remained consistent between pretesting sessions for all patients. After intervention, though, patients in the CIT group exhibited substantial improvement on the Fugl (**Table 2**), while TR and CON patients exhibited few improvements.

¹To keep contact times consistent, informal in-clinic interviews were also conducted with patients in TR to see if their therapy was satisfying to them. Telephone calls were also made to the homes of patients in TR and CON to further keep contact time consistent.

Table 2.Scores of CIT patients on the Fugl and ARA before and after intervention.

	CIT						Traditional						Control						
		1			2			3			4			5			6		
	PR1*	PR2+	POS#	PR1	PR2	POS	PR1	PR2	POS	PR1	PR2	POS	PR1	PR2	POS	PR1	PR2	POS	
Fugl	47	48	55	33	37	46	53	53	47	60	59	64	55	51	53	62	62	61	
Fugl ARA	49	48	59	24	29	47	40	33	35	56	55	63	39	40	41	61	60	61	

^{*} PR1 denotes score obtained during first pretesting period. + PR2 denotes score obtained during second pretesting period. # POS denotes score obtained during posttest.

All subjects also displayed consistent scores on the ARA during pretesting, but subjects in the CIT group exhibited appreciably improved functional scores after intervention (**Table 2**). TR and CON patients' levels of arm function, as measured by the ARA remained relatively stable and decreased, in some cases, after intervention.

Subjects in the CIT group also displayed substantial improvements on the WMFT between pretesting and posttesting sessions, both in terms of rating of movement and time taken to complete the movement (**Table 3**). In contrast, subjects in the TR and CON groups displayed few, if any, improvements between pretesting and posttesting sessions as measured by the WMFT.

Using the MAL, patients exhibited substantial changes, both in amount of use of the affected arm and quality of use of the affected arm between PRE and POST (**Table 4**). Specifically, before intervention, patients in all three groups reported using the affected arm for between 1 and 3 of the 30 tasks listed on the MAL with average quality of use ratings of 2.0, 2.8, and 2.7 for the CIT, TR, and CON groups, respectively. In contrast, at POST, patients in the CIT group reported using the affected arm for an average of 14.0 activities with a QOU rating of 4.3. In contrast, AOU scores for TR changed by 3.0 and 1.0 for the TR and CON groups, and QOU scores changed by 1.0 and 0.2 for subjects in the TR and CON groups, respectively.

User ratings by each subject's spouse or caregiver, QOU scores prior to intervention were 3.1, 3.3, and 2.9 for the CIT, TR, and CON groups, respectively. AOU scores prior to intervention were 5.2, 6.1, and 5.8 for the CIT, TR, and CON patients, respectively. At POST, QOU scores were 4.5, 2.9, and 3.0 for patients in the CIT, TR, and CON patients, respectively. AOU scores after intervention were 15.0, 6.0, and 5.0 for caregivers of individuals in the CIT, TR, and CON groups, respectively.

DISCUSSION

The traditional CIT protocol, although efficacious, may be less feasible in the eyes of some therapists and/or patients. Pilot data obtained by Page and colleagues (16) demonstrated reductions in impairment and increases in arm use and function in a patient with subacute CVA who participated in a modified CIT protocol. The present study attempted to gauge the feasibility and compare the efficacy of a modified clinically practical CIT protocol with a traditional regimen of physical/occupational therapy, and with no therapy in reducing upper-limb impairment and improving outcomes in the affected arm of patients with subacute CVA.

With regard to feasibility, adherence, and satisfaction among CIT patients, each were high. Specifically, one CIT patient recorded only one incidence of not wearing the sling over the 10-week period. These data were corroborated by each patient's caregivers. Informal interviews also revealed that participating therapists found the protocol easy to administer, particularly since PNF and compensatory training were already part of their treatment regimens for patients with CVA. This finding was in contrast to the survey by Page and colleagues (14), which indicated that therapists felt that CIT was difficult to administer, and not implementable within most clinical environments without special training and/or additional resources.

Prior to intervention, all patients exhibited stable scores during two separate administrations of the Fugl and ARA. However, after intervention, subjects receiving modified CIT exhibited substantial increases in arm function and reductions in arm impairment, as measured by the ARA and Fugl, respectively. Considerable changes were also observed among CIT subjects between pretesting and posttesting sessions on the WMFT, both in terms of rating of arm use, and in terms of time taken to complete the task. In contrast, patients in the TR and CON

Table 3.Ratings of task performance and time taken to complete each task on the WMFT at PRE versus POST.

					Cl	T						ı	Trad	ition	al						Cont	rol		
		_	1				2				3				4				5				6	
		PRE	2	POS	ST	PRE	2	POS	\mathbf{T}	PR	E	POS	T	PRI	E	POS	T	PRE		POS	Г	PRE	I	POST
Task	R*	T +	R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T	R	T
Forearm to table	3	2	4	2	3	5	5	1	3	3	4	5	5	1	5	1	4	3	4	3	3	5	3	5
Forearm to box	1	5	4	10	3	8	4	5	3	3	3	5	5	1	5	1	4	3	4	3	3	5	3	5
Extended elbow	4	3	5	5	3	8	4	5	4	3	4	5	5	1	5	1	4	1	4	1	4	5	4	5
Extended elbow w. weight	3	3	4	5	2	9	4	5	4	3	3	10	5	1	5	1	5	3	5	5	3	10	3	5
Hand to table	4	2	4	1	4	10	5	5	4	2	4	5	5	3	5	3	5	2	5	5	4	5	4	5
Hand to box	1	5	4	5	3	5	4	5	4	2	4	5	5	4	5	4	5	2	5	5	4	8	4	5
Weight to box	3	2	4	5	3	8	4	5	3	3	4	3	4	4	4	4	5	2	5	5	3	10	3	8
Reach and retrieve	3	6	5	2	3	10	4	10	3	3	3	3	5	1	5	1	4	5	4	5	4	10	3	10
Lift can	4	1	5	2	4	8	4	5	2	6	3	10	5	1	5	1	4	5	4	5	4	3	3	5
Lift pencil	3	4	4	1	4	3	4	5	0	20	1	5	5	1	5	1	4	5	4	5	3	5	3	10
Lift paperclip	5	3	4	1	4	6	4	5	0	20	1	10	5	1	5	1	2	10	3	5	2	10	2	5
Stack checkers	5	3	5	1	3	4	4	5	0	20	1	10	5	1	5	1	3	7	3	5	3	8	2	5
Flip cards	2	3	4	2	3	5	4	5	0	20	0	20	5	1	5	1	3	10	3	5	3	7	3	5
Grip strength	3.9	NA	4.3	NA	3.8	NA	4	NA	4.1	NA	4.2	NA	4.5	NA	4.5	NA	4.9	NA	4.9	NA	3.7	NA	3.7	NA
Turn key in lock	3	5	5	5	4	2	5	10	3	3	2	5	5	1	5	1	4	5	4	5	4	5	4	5
Lift basket	1	5	4	5	4	4	4	5	3	3	2	5	5	1	5	1	4	5	4	5	3	10	3	10
Average	3	3.4	4.3	3.4	3.3	6.3	4.3	5.1	2.4	7.3	2.7	6.9	4.9	1.5	4.9	1.5	4	4.6	4.1	4.5	3.3	6.9	3.1	6.1

^{*} R denotes observer rating of patient ability to complete each task. + T denotes time taken, in seconds, by patient to complete the task. Patients were given 120 seconds to complete each task with one trial provided for each task. Averages do not include grip strength amount, measured in kilograms. NA=denotes tasks on which time was not recorded.

Table 4.Changes in self-ratings of amount and quality of affected arm use between PRE and POST group.

	I	PRE	PO	ST
Group	Average amount of use	Average quality of use	Average amount of use	Average quality of use
CIT	2	2.0	14	4.3
TR	1	2.8	5	3.0
CON	3	2.7	3	2.2

Scores on the scales are based on a subjective rating scale, with 0 being the lowest rating and 5 being the highest.

groups exhibited no changes between pretesting and posttesting sessions. Patients in the CIT group showed especially strong improvements on the "shaping" tasks on the WMFT. Although improvements were seen in some of the gross items featured on each instrument, the most remarkable improvements among patients in the CIT group were displayed on fine motor skills (e.g., wrist movements on the Fugl; gripping and grasping movements on the ARA; turning cards, stacking checkers, picking up a paperclip on the WMFT).

Patients in the CIT group also displayed considerably larger improvements in the use and function of their affected arms, as measured by the MAL, than those in the TR or CON groups. These MAL scores are the first to suggest that the learned nonuse phenomenon observed in all patients at PRE can be overcome through a modified training and sling wear schedule still emphasizing repeated use. A shortcoming of rehabilitative studies in general has been a paucity of data describing the transfer of the treatment effect to the life situation. In this study,

informal interviews conducted after intervention with patients assigned to CIT revealed a positive transfer of skills learned in rehabilitation to ADLs. Specifically, one patient was able to subsequently enroll in a driver rehabilitation program, was able to begin cooking again, and was able to play with her grandchildren again. The other patient noted that, following intervention, he was able to return to his work as a carpenter as well as perform work around the home. He also described improvements in aspects of his relationship with his wife and family. Taken together, these data further support the supposition that combining restraint of the unaffected limb with the therapy protocol described herein overcomes the learned nonuse phenomenon, resulting in increases in arm use and function and reductions in impairment of the affected upper limb after CVA. Evidence also suggests that this protocol is more efficacious than both traditional therapy alone and no therapy.

Research with patients with CVA is often confounded by natural recovery among subjects. However, several factors make natural recovery an unlikely explanation for the effect observed: (1) all subjects had been discharged from all forms of therapy for a minimum of 1 month (mean 3.8, range 1 to 4 months); (2) comparison between our observations at initial screening with medical records, discharge summaries, and physiatrist observations suggested that patients had not exhibited improvement since time of discharge from therapy; (3) our multiple baseline pretesting design showed no appreciable changes among any of the subjects prior to intervention; (4) the rapid progress that patients receiving modified CIT exhibited in a relatively short amount of time, particularly in comparison to TR and CON patients, also makes it unlikely that improvements were attributable to spontaneous recovery. We can, thus, with a fair amount of confidence, rule out the possibility of natural recovery as an explanation for the observed effects.

CONCLUSION

For many patients with CVA, participation in the traditional CIT protocol may be problematic, given the intensity of the practice schedule and the duration of the restraint schedule. Problems with the restraint schedule, such as inability to use the affected arm and hand for balance activities and instrumental ADLs, may also cause problems. Therapists have also noted that the practice schedule and restraint schedule in CIT could make patient

adherence and motivation, as well as ability to engage the patient over 6 hours, problematic. At the same time, most therapy centers and subacute facilities have patients with CVA who exhibit learned nonuse and who are receiving traditional therapy regimens on an outpatient basis. Although the CIT protocol is based on massed, repeated practice, there is much motor learning evidence suggesting that various types of practice schedules can facilitate motor learning (15,25,26). Findings in the current study provide evidence suggesting that a modified CIT protocol using a more distributed practice schedule but still emphasizing repeated use is effective in reducing upper-limb impairment and improving upper-limb use and function. It is possible that repeated affected limb ADL practice, which is a deviation from current clinical practice, may be the critical variable in overcoming learned nonuse, while the practice schedule (e.g., massed or distributed) may be less crucial. Given data presented here, we would encourage randomized, controlled studies of modified CIT with patients with CVA exhibiting learned nonuse.

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